

REMARKS1. Status of the Claims

Claims 1-50 were originally filed in the application. Claims 36-38 are canceled herein. Therefore, claims 1-35 and 39-50 are currently pending in the present application. Reconsideration in view of the amendments above and the remarks below is respectfully requested.

2. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 1-6, 8-24, 28, 36-41, and 43-45 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The present rejection is respectfully traversed.

A. Claims 1, 24, and 39

The Examiner asserts that in claims 1, 24, and 39, and claims which depend therefrom, the term "resistance" is allegedly "ambiguous because 'resistance' is a functional term which can have different meanings depending on how the function is defined and measured", and therefore, claims 1, 24, and 39 are allegedly indefinite. The present rejection is respectfully traversed.

A decision on whether a claim is indefinite requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. Seattle Box Co. v. Industrial Crating & Packing Inc., 221 USPQ 568, 574 (Fed. Cir. 1984). It is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim. E.I. Du Pont & Co. v. Phillips Petroleum Co., 7 USPQ2d 1129 (Fed. Cir. 1988). The test is whether one of ordinary skill in the art can determine with a

reasonable degree of certainty what would be infringing and what would not. In re Marosi, 218 USPQ 289 (CAFC 1983); and In re Miller, 169 USPQ 597 (CCPA 1971).

The term "resistance" is defined in the specification, e.g., at page 7, lines 2-4; which states, "By inhibiting virus spread, the virus infection is reduced and/or blocked, thereby increasing plant 'resistance' to the virus infection". In view of the claims and the specification, the meaning of "resistance" is clear to one of ordinary skill in the art such that the artisan can determine whether or not the claim is infringed. Therefore, the term "resistance" as used in claims 1, 24, and 39 is definite.

B. Claims 1-24

The Examiner asserts that claims 1-24 are incomplete method claims, allegedly "because the final step of the recited method does not result in the production of the desired product", and therefore, implies that the claims are allegedly indefinite for this reason. The present rejection is respectfully traversed.

Applicants respectfully submit that claims 1-24 are not indefinite because the step of introducing a ssDNA-binding protein of the Inoviridae virus family into a plant produces in the plant a resistance to a ssDNA virus. For example, the specification demonstrates that resistance to a ssDNA virus is produced by introducing a ssDNA-binding protein of the Inoviridae virus family in Example 7 starting on page 35 with results shown in Table 2 starting on page 33.

C. Claim 13

The Examiner asserts that claim 13 is indefinite because it allegedly does not have a period at the end of the sentence. In

view of the amendment to claim 13, the present rejection is believed to be moot.

D. Claims 4, 19, 20, 21, and 28

The Examiner asserts that the meaning of the marks "/", "//", and "]" are allegedly unclear, and therefore, implies that the claims are indefinite.

In claims 4 and 28, the terms "ZG/2" and "ZJ/2" are art recognized terms designating certain species of Coliphage virus. Accordingly, claims 4 and 28 are not indefinite because the mark "/" found in claims 4 and 28 is part of an art recognized term.

In claims 19, 20, and 21 the marks "/" and "//" are art recognized designations used to indicate a field strain of the ssDNA virus. Accordingly, claims 19, 20, and 21 are definite with respect to the use of the marks "/" and "//" because these marks are art recognized terms.

The marks "[" and "]" have been amended to denote parentheses "(" and ")" respectively. Thus, Applicants believe that the rejection based upon the marks "[" and "]" is moot.

E. Claims 36-39

The Examiner asserts that claims 36-39 are indefinite because the element "said ssDNA virus" allegedly lacks antecedent basis. Claims 36-38 are canceled herein without prejudice or disclaimer. In view of the cancellation of claims 36-38, the present rejection is believed to be moot with regard to claims 36-38.

Claim 39 is an independent claim and does not recite the element "said ssDNA virus". Applicants submit that the rejection

of claim 39 based on lack of antecedent is inappropriate, and requests that the rejection be withdrawn.

F. Claim 39

The Examiner asserts that the term "effective amount" recited in claim 39 renders claim 39 indefinite. The present rejection is believed to be moot in view of the amendment to claim 39 that cancels the term "effective amount", and therefore, it is requested that the rejection be withdrawn.

3. Claim Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 1-6, 8-30, 32-41, 43-48, and 50 under 35 U.S.C. § 112, first paragraph alleging that the claims fail to comply with the enablement requirement. Applicants respectfully traverse the present rejection.

The response will be divided into sections identical to the sections put forth in the Office Action mailed November 19, 2003.

Re "resistance"

The Examiner asserts that the "Applicant claims a method of producing plant resistance to any ssDNA virus by introducing a ssDNA of any Inoviridae virus into the plant" (see the bottom of page 4 of the Office Action mailed November 19, 2003; hereinafter the "Office Action"). However, claim 1, for example, recites "A method for producing in a plant resistance to a single stranded DNA (ssDNA) virus comprising introducing a ssDNA-binding protein of the Inoviridae virus family into said plant" (emphasis added). Thus, it is the ssDNA-binding protein of the Inoviridae virus family that confers resistance, not the ssDNA virus as asserted by the Examiner.

The Examiner further asserts that, "Applicant gives no working definite [sic] of resistance" (see the first paragraph of page 5 of the Office Action). As discussed above, the specification defines resistance at page 7, lines 2-4; which states, "By inhibiting virus spread, the virus infection is reduced and/or blocked, thereby increasing plant 'resistance' to the virus infection".

The Examiner next asserts that, "While Applicant's results indicate that plants expressing M13 gene 5 protein develop mild symptoms in response to geminiviruses and slows viral movement, Applicant's results do not indicate that the plant is completely resistant, as claimed".

Applicants respectfully submit that the Examiner is correct in that the results do demonstrate that plants expressing M13 gene 5 protein develop mild symptoms in response to Geminiviruses and viral movement is slowed compared to plants that do not receive treatment. These results, in fact, are evidence that resistance to a ssDNA virus is produced in plants by introducing a ssDNA-binding protein of the Inoviridae virus family into said plants.

The Examiner further asserts, "Applicant's results do not indicate that the plant is completely resistant, as claimed". The claims, however, do not recite the element "completely resistant". Therefore, the present rejection of the term "resistance" is misapplied and should be withdrawn.

Re "any ssDNA virus" and "ssDNA of any Inoviridae"

The Examiner asserts that, "the M13 gene 5 protein is special (specification, page 41) and is not representative of all ss binding proteins" (see the first line of page 6 of the Office

Action). Applicants respectfully submit that nowhere in the specification is the M13 gene 5 protein said to be "special". Nor does the specification state that M13 gene 5 protein "is not representative of all ss binding proteins".

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. For the reasons discussed below, it is believed that the results described in the present application can fairly be extrapolated to the use of any ssDNA-binding protein of the Inoviridae virus family to confer protection against any ssDNA virus.

The present application is based on the discovery that the Coliphage M13 gene 5 product is capable of making plants resistant against infection by several different geminiviruses. Geminiviruses, like all ssDNA ssDNA viruses, replicate in the nucleus of the infected cell, where the single-stranded viral genome is synthesized and then exported to the cytoplasm for encapsidation by the viral coat protein. Results shown in the present application indicate that the gene 5 protein interferes with this process by binding to the ssDNA thereby inhibiting transport to the cytoplasm.

Single stranded DNA viruses having a circular genome infect bacteria, mycoplasma, spiroplasma, vertebrates (including humans) and plants; and all share a similar type of genome organization. Most importantly, all have a similar type of cycle in the infected cell, involving a ssDNA phage (see e.g., page 1, line 33 through page 2, line 5).

The normal function of the M13 gene 5 protein is to bind to the single-stranded genome of the M13 coliphage. The fact that a

protein derived from a bacterial virus is capable of binding to ssDNA of several different plant viruses indicates either that this binding is not sequence-specific, or that the binding target is highly conserved amongst ssDNA viruses (see, e.g., page 37, line 11 through page 38, line 2 and page 41, lines 10-27). In either case, it is eminently reasonable to predict that the gene 5 protein will be similarly capable of binding to any single-stranded viral genome, thereby inhibiting replication. Indeed, given the findings of the present inventors with the M13 gene 5 product and geminiviruses, it would be most surprising if this were not so. Meanwhile, the Examiner has offered no evidence on the record to the contrary.

The outstanding question is whether the results obtained with the M13 gene 5 protein can properly be extrapolated to ssDNA binding proteins of other Inoviridae viruses. In this regard, Applicants respectfully submit that these results can be properly extrapolated as discussed below.

The M13 gene 5 protein is widely regarded as a "model" ssDNA binding protein. It has a DNA binding loop which is highly homologous to that of the ssDNA binding proteins of other Inoviridae viruses such as IK3 and Pf3 (de Jong et al. (1989) J. Mol. Biol. 206:133-152). Moreover, alignment of the amino acid sequence of the ssDNA-binding proteins of M13, IKe and Pf3 with those of the ssDNA-binding protein of the filamentous phages T4, Pfl1, and Phi29 strongly suggest that similarly structured DNA-binding loops are present in these proteins.

If such disparate viruses as Phi29, IKe, and T4 have ssDNA-binding proteins which are closely related to the M13 gene 5 protein, and binding of the M13 gene 5 protein to ssDNA is not virus-specific (as discussed above), then the overwhelming

likelihood is that these other ssDNA-binding proteins are similarly non-specific in their binding, and that they will therefore be capable of binding to any single-stranded viral genome to inhibit replication and confer resistance to infection. It is therefore, eminently reasonable to predict that any ssDNA-binding protein of any Inoviridae virus can be used in the present invention to confer resistance to any ssDNA virus in a plant.

Next the Examiner asserts at page 6, last paragraph of the Office Action that, "Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden".

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation.

As discussed above, the specification discloses a model system in which resistance to Tomato leaf curl virus (ToLCV) is conferred by introducing M13 gene 5 protein into *Nicotiana tabacum* protoplasts and *N. benthamiana* plants. This is a working example which provides a model for testing resistance to other geminiviruses by introducing a ssDNA binding protein of the Inoviridae virus family into other plants. In other words this same procedure can be repeated to test resistance to any other geminivirus by introducing a ssDNA binding protein of any other Inoviridae virus family into any other plant. The Examiner has not provided any evidence that such repetition results in undue

experimentation. Applicants respectfully submit that repetition of an experiment does not result in undue experimentation. Therefore, the invention is enabled over the entire scope of the claims because one of ordinary skill in the art can make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. Accordingly, the present rejection should be withdrawn.

CONCLUSION

Claims 1-35 and 39-50 are currently pending. The Applicants respectfully traverse all claim rejections. The Applicants respectfully submit that all pending claims are in condition for allowance and request that the Examiner allow all pending claims.

No new matter is added by way of the present Response.

The Examiner is requested to contact the representative for the Applicants, to discuss any questions or for clarification.

If there are any further fees associated with this response, the Director is authorized to charge our Deposit Account No. 19-0962.

Respectfully submitted,

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Date

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